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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,552	12/02/2000	Kong-Hong Andy Choo	11445Z	3587

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EXAMINER	
QIAN, CELINE X	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/728,552	CHOO ET AL.	
	Examiner	Art Unit	
	Celine X Qian	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-74 is/are pending in the application.

4a) Of the above claim(s) 9,10,22,23,35,36,48-60,69 and 70 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8,11-21,24-34,37-47,61-68 and 71-74 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 27 December 2002 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/078,294.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Notice to comply

DETAILED ACTION

Claims 1-74 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 6/18/04 is acknowledged. The traversal is on the ground(s) that the invention of Group I and II are related. Applicants argue that the artificial chromosome of Group II is a form of the genetic construct of Group I. Applicants further assert that the nucleic acid comprising a neocentromere of Group I permit the development of the artificial chromosome of Group II. Applicants thus conclude that the invention of Group I and II are not independent and distinct, but are linked to each other as different aspects of a single invention. Furthermore, Applicants argue that nucleic acid molecules comprising a sequence as set forth in SEQ ID NO:3-29 are all related to each other as molecules that can function as a centromere, and they represent different regions of normal or mardel neocentromere. Applicants thus conclude that they are different aspects of a single invention. Moreover, Applicants argue that the courts have recognized that it is in public's interest to permit applicants to claim several aspects of their invention. Lastly, Applicants argue that in light of increasing official fees and potential double patenting issue, the restriction requirement should be withdrawn to protect applicant's legitimate patent rights.

These arguments has been fully considered and deemed unpersuasive. The inventions of Group I and II are patentably distinct for reasons set forth of the record mailed on 1/16/04. The nucleic acid of Group I read on any natural occurring or synthetic chromosome or a nucleic acid fragment that comprises a neocentromere of any kind, which is distinct from the invention of Group II that is drawn to an artificial chromosome which would confer a phenotypic property on

a cell. They are not capable of being used together and have distinct function. The artificial chromosome of Group II is used in gene therapy whereas the isolated nucleic acid may be used for transfecting large fragments of DNA *in vitro* assay. Although the invention of Group I may be used to develop the artificial chromosome of Group II, they clearly have different scope. A search of Group I and II would not be co-extensive. The nucleotide sequences of SEQ ID NO: 3-29 have different structures, i.e. sequences, that does not render obvious of each other. It would have been burdensome to search all the sequences in a single application.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 9, 10, 22, 23, 35, 36, 48-60, 69 and 70 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1-8, 11-21, 24-34, 37-47, 61-68, 71-74 are currently under examination.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Sequences are disclosed in the specification and/or figures that are not identified by their sequence identifier (i.e., SEQ ID NO:). For example, in Figure 16, several nucleic acid sequences are disclosed, but none are identified by their sequence identifier. The Brief Description of the Drawings at page 10 and 11 also does not identify the sequences by SEQ ID NO. **Applicant is reminded that the entire specification and figures should be reviewed for**

sequence disclosures and that each sequence disclosed in the specification must be identified by its sequence identifier (i.e., SEQ ID NO:). The specification must be amended to identify all disclosed sequences by their sequence identifier (i.e., SEQ ID NO), in accordance with 37 CFR 1.821(d).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 11-14, 15-21, 24-27, 28-34, 37-39, 40-47, 61-68, 71-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is set forth by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . .[emphasis added]." The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the

claimed invention." See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

In analyzing whether the written description requirement is met, it is first determined whether a representative number of species have been described by their complete structure. Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. The claims recite "a neocentromere or a functional derivative, synthetic or hybrid form", "chemical equivalent," and "mammalian or non-mammalian homologue." The specification teaches that a "neocentromere" is referred to a new form of centromere (see page 3, lines 25 and 26). This term thus potentially encompasses a large number of nucleic acid of various size and origin which function as a centromere, and is a new form. However, the specification only disclose one such "neocentromere" isolated from human chromosome 10 represented by SEQ ID NO:3. The specification does not describe any other new form of centromere, neocentromere(s), that has the same function as the one represented by SEQ ID NO:3. Further, the specification fails to describe any functional derivative, (or derivative of any kind), chemical equivalent, natural or synthetic, mammalian or non-mammalian homologue that has the same function. Moreover, the specification fails to describe what is the critical structure (i.e. the sequence) which is necessary for its function as a neocentromere. As such, the specification fails to describe a representative species by their complete structure and other identifying characteristics. Claims 11-14, 24-27, 37-39 and 71-74 recites the nucleic acid comprising sequence from the neocentromere is between 50bp-1500kb, 1kb-1000kb, 10kb-500kb, or 10kb-100kb. Since the specification only describe a nucleic acid comprising a neocentromere (SEQ ID NO:3) of 80kb in length without teaching the critical

structure for its function, the specification fails to describe any fragments (such as 50bp, 1kb, 10kb) of said nucleic acid that would have the same function. Thus the specification fails to describe the claimed genus by their complete structure and other identifying characteristics.

Claims 5, 18, 31, 44 and 65 recite a nucleic acid derived from "a modified form of human chromosome 10 or its non-human mammalian or non-mammalian equivalent." As discussed above, the specification only disclose a neocentromere comprising nucleic acid isolated from human chromosome 10 represented by SEQ ID NO:3. The specification fails to describe nucleic acid isolated from other modified human chromosome 10 except Mardel. The specification also fails to describe any other nucleic acid that is isolated from any mammalian or non-mammalian equivalent that has the same function as the neocentromere of SEQ ID NO:3. As such, the structural and functional relationship of the claimed nucleic acid and its function is missing.

Claims 21, 34, 47 and 68 recite "a nucleic acid sequence substantially as set forth in SEQ ID NO:3 or a nucleic acid sequence having at least 40% similarity thereto or a nucleotide sequence capable of hybridizing to SEQ ID NO:3 under low stringency conditions at 42C." This potentially encompasses a large group of nucleic acids of various size and origin that share some homology with SEQ ID NO:3. However, since the specification only disclose the sequence of one neocentromere represented by SEQ ID NO:3, and lack of description of the functional elements within said nucleic acid, it is unclear whether the claimed genus of nucleic acids would have the same neocentromere function. Therefore, the specification fails to describe the claimed invention in such a way to convey one skilled in the art that the inventors had possession of the invention at the time the application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 11-14, 15-21, 24-27, 28-34, 37-39, 40-47, 61-68, 71-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1-8, 11-14, 15-21, 24-27, 62 and 63, the term "derived" renders the claims indefinite because the nature and number of the derivative process is unknown. As such, the metes and bounds of the claim cannot be established. The term "derivative" also renders the claims indefinite because it is unclear what is the nature of such derivative. In other words, it is unclear what physical, chemical or biochemical feature such derivative must have to qualify as a nucleic acid derivative.

Regarding claims 1-8, 11-14, 15-21, 24-27, 28-34, 37-39 and 40-47, the term "hybrid form thereof" renders the claim indefinite because the nature of such hybrid form is unknown. In other words, it is unclear what substance the nucleic acid is hybrid with.

Regarding claims 5-8, 18-21, 31-34, 44-47, 65-68, the recitation of "a modified form of ...its non-human mammalian or non-mammalian equivalent" renders the claim indefinite because it is unclear what is the nature of such equivalent. It is unclear whether such equivalent is a chromosome or a neocentromere. It is also unclear whether such equivalent is a equivalent of human chromosome 10 or a modified form of said chromosome.

Regarding claims 6, 8, 19, 32 and 66, the recitation of "nucleotide sequence corresponds to a region" renders the claim indefinite because it is unclear what is the relationship between the nucleotides sequence and the region. In other words, does it have to share homology with this

region, isolated from that region, or recombines with this region. As such, the metes and bounds of the claim cannot be established.

Regarding claims 8, 21, 34, 47 and 68, the term "substantially as set forth" renders the claim indefinite because it is unclear what is the metes and bounds would be considered substantially set forth.

Regarding claims 4-8, 17-21, 30-34, 43-47, 64-68, the recitation of "capable of associating with centromeric binding protein..." renders the claims indefinite because it is unclear what is the relationship between the nucleic acid and the binding protein. It is unclear whether the nucleic acid binds to the protein, encodes the protein or linked to the protein. The recitation of "capable of associating with centromeric binding protein...or antibodies thereto" also renders the claims indefinite because it is unclear if the antibodies are anti-nucleic acid antibodies or anti-binding protein antibodies.

Regarding claims 28-34 and 37-39, the term "chemical equivalent" renders the claim indefinite because the nature of such equivalent is unclear.

Regarding claims 29-34, the recitation of "a compatible cell" renders the claim indefinite because it is unclear what the requirement for the cell to be compatible with the nucleic acid.

Regarding claims 61-67 and 71-74, the term "defines" renders the claim indefinite because it is unclear how a nucleotide can "define" a neocentromere. Does it mean it encodes a neocentromere or associates with a neocentromere?

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 11-14, 15-21, 24-27, 28-34, 37-39, 40-47, 61-68, 71-74 are rejected under the judicially created doctrine of double patenting over claims 1-7, 10-15, 18-24, 27-32 of U. S. Patent No. 6, 265,211 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The claimed invention and the issued claims are directed to the same subject matter. The pending claims have a broader scope and thus are anticipated by claims 1-7, 10-15, 18-24, 27-32 of patent 6,265,211.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.